EndoSheath® Technology
Infection Control Considerations

The reasons to consider using EndoSheath® Technology rather than conventional flexible scopes requiring high level disinfection between uses are numerous. The material in this binder relates to minimising the risk of cross-infection.

The Vision Sciences flexible endoscopes do not incorporate a working channel. Instead, following a prescribed aseptic protocol, they are fitted with a disposable sterile sheath which incorporates the working channel. In this way the patient is not exposed to a contaminated surface.

The following pages comprise:

1) A leaflet explaining EndoSheath® Technology

2) Aseptic EndoSheath technique (wall charts)

3) A 21st century nosocomial issue with endoscopes
BMJ 2014; 348 doi: http://dx.doi.org/10.1136/bmj.g2047 (published 19 MArch 2014)

4) A comparison between "sterilised" cystoscopes and disposable sterile sheaths
Steve McCombie, Sarah J. Wood et al. (Norfolk & Norwich University Hospital)
Journal of Clinical Urology Feb 2013

5) Outpatient Flexible cystoscopy using a disposable slide-on Endosheath system
M Kimuli, S Lloyd Ann R Coll Surg Eng, 2007: 89: 426-430

6) Microbiologic Assessment of Disposable Sterile Endoscopic Sheaths
Alvarado CJ et al Am J Infect Control 2009;37:408-13

7) Endoscope Sheaths as Viral Barriers: Laboratory FDA Study
Baker KH et al Laryngoscope 1999;109:636-9

8) Relevant points in CfPP 01-06 guidelines

Contact Genesis Medical for further information, a PowerPoint presentation on the Infection Control considerations, copies of referenced papers, a bibliography of relevant peer reviewed papers. Much material is available on the website: www.genmedhealth.com

April 2014

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Infection Control
with EndoSheath® Endoscopy

EndoSheath® Technology

The sterile, disposable solution for flexible endoscopy

EndoSheath® Technology is not your typical barrier. Designed to offer a strong, durable, proven effective microbial barrier, this is not just a simple cover. By providing a barrier between the endoscope and patient, EndoSheath® Technology allows for less complicated cleaning and disinfection routines, and improves equipment turnaround time. All the difficult-to-clean endoscope components with EndoSheath® Technology are disposable, including: the barrier, the channels, the ports, and the seals. Clinically proven, EndoSheath® Technology allows for efficient, effective endoscope reprocessing in any setting.

With *EndoSheath® Technology* there is strength in numbers…

- **20+** years on the market
- **30+** FDA clearances
- **37+** systems with CE Mark
- **9+** systems with HealthCanada license
- **5+ million** procedures performed worldwide
- **0 cross-contamination complaints**

Reusable Endoscope

with sterile, disposable EndoSheath® Technology

EndoSheath® Technology

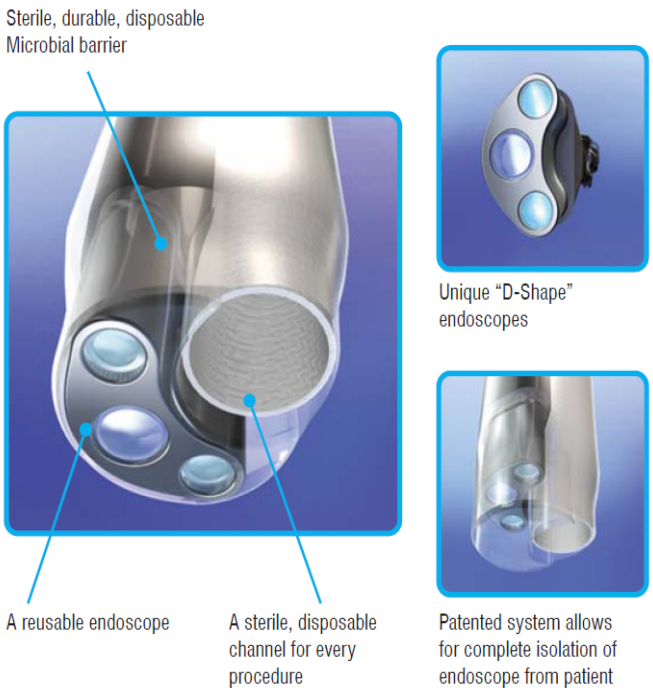
A brand with strength.
A name you can trust.

Pioneering Infection Control
with EndoSheath® Endoscopy

EndoSheath® Advantages:

- EndoSheath® Technology is a proven effective barrier to organisms as small as 27 nanometers per FDA requirements and testing
- Over 5 Million EndoSheath® products sold over 20 years without a single reported complaint of patient-to-patient cross contamination
- EndoSheath® Technology is designed to stretch and maintain its integrity, and not to tear or break during procedures
- All EndoSheath® disposables are 100% leak tested during manufacturing with a 0% acceptable failure rate for production
- All barriers, channels, ports, seals, and tubing are sterile and disposable
- Concerns over biofilm, bioburden, and issues of improperly rinsed devices are eliminated for patient contact areas, as they are always new, sterile, and disposable
- Easy to use and prepare limiting the complexity of endoscopy preparation routines
- Compatible with standard accessories such biopsy forceps, needles, and other endoscopic devices
- Over 30 research studies performed on EndoSheath® Technology since 1992
- Disposables feature a 3-year shelf life
- EndoSheath® Technology is FDA cleared and CE marked

Innovative Solutions:


Sterile, durable, disposable
Microbial barrier
A reusable endoscope
A sterile, disposable channel for every procedure
Unique "D-Shape" endoscopes
Patented system allows for complete isolation of endoscope from patient

About Vision-Sciences, Inc.

Vision-Sciences,Inc. has brought pioneering concepts to the world of flexible endoscopy for over 20 years. With the patented EndoSheath® Technology and innovative endoscope designs, Vision-Sciences,Inc. has transformed the economics of flexible endoscopy while enhancing patient safety for Otolaryngology, Gastroenterology, Urology, and Pulmonology practitioners. Vision-Sciences has made a commitment to help physicians transform their practices with the EndoSheath® Technology.

Currently available for:
Bronchoscopy, Cystoscopy, Esophagoscopy, and Laryngoscopy

Request a **Clinical Research Summary** or an Official EndoSheath® Technology **Infection Control package:**

Call **800-874-9975** or visit **www.visionsciences.com**

Vision-Sciences, Inc.
40 Ramland Road South / Orangeburg, NY 10962
Telephones: 800-874-9975 / 845-365-0600 / Fax: 845-365-0620
E-Mail: info@visionsciences.com

CE 0843

www.visionsciences.com

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Vision Sciences Endoscopes and EndoSheath ® Technology Preparation Wall Chart

PRECAUTIONS:

- Endoscopes and EndoSheath® Technology should not be used without a thorough review and understanding of the User's Manual.
- Before inserting the Endoscope into the Sheath, ensure that the insertion Tube is Clean, Dry and Undamaged.
- Review the User's Manual for Recommended Cleaning procedures for the Endoscope.
- If setting up for sterile field, double-glove with sterile gloves.

BEFORE THE PROCEDURE - SET UP

STEP 1

Carefully place Sheath contents in sterile field.

STEP 2

Double glove, Sterile. Apply drape bag to installation stand

STEP 3

Place Sheath into installation stand with accessory port facing out

STEP 4

Gently insert Scope into Sheath with the endoscope label facing forward and the flat edge of the insertion tube against the flat edge of the Sheath connector opening

IMPORTANT NOTE

The tip of the scope MUST be straight when placing into Sheath. If there is any resistance in loading, verify that the Sheath channel is properly aligned. If the channel is misaligned / twisted, straighten the channel before continuing scope insertion

STEP 5

Lock Sheath to Scope by turning knob 90⁰ (horizontal)

STEP 6

Deflect Scope tip to ensure Sheath window is seated properly.

STEP 7

When applicable insert irrigation/suction tube through the flow control valve.

STEP 8

Attach the end of the irrigation/suction tube to an irrigation/ suction source.

IMPORTANT NOTE

When using a CV-1.5 Sheath, attach the irrigation source tubing directly to the sheath connector accessory port.

STEP 9

If setting up sterile, remove outer gloves. Unfold cover over control body of Scope and secure with clips.

STEP 10

Ready for use. Verify angulation function and water flow/suction before use.

AFTER THE PROCEDURE - REMOVAL

STEP 11

Double glove before starting removal process. Re-insert Scope into stand, detach clips and move control Body Cover without contaminating handle. Remove outer gloves.

STEP 12

Detach irrigation/ suction Tube from the Flow Control Vale and Water Source.

STEP 13

Unlock Sheath rom Scope by Turning the Locking Knob to the Vertical Position.

STEP 14

Remove Scope from Sheath.

IMPORTANT NOTE

If resistance is felt during removal. STOP, Make sure the sheath and Scope are STRAIGHT and ensure the channel is not wrapped around the insertion tube. Use the drape bag as a barrier between the fingers and sheath, gently grasp the window of the Sheath and remove the Scope WITHOUT rotating the Scope

STEP 15

Deposit used Sheath and gloves into drape bag and dispose as per hospital policy.

EndoSheath® Technology

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Vision-Sciences, Inc.
40 Ramland Road South / Orangeburg, NY 10962
Telephones: 800-874-9975 / 845-365-0600 / Fax: 845-365-0620
E-Mail: info@visionsciences.com

Genesis Medical Ltd
7 Trojan Business Park
Cobbold Road
London NW10 9ST
Tel: +44 (0)20 8451 4100
Fax: +44 (0)20 8451 4115
Website: www.genmedhealth.com

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Endoscope with EndoSheath® Technology

Reprocessing Chart for Recommended Cleaning Procedure

The EndoSheath® Technology is a sterile, disposable, durable protective barrier which isolates an endoscope from patient contact, and limits the need for elaborate chemical disinfection or EtO sterilization procedures after every endoscopy procedure. EndoSheath® Technology allows for fast and effective reprocessing of an endoscope and ensures a sterile Insertion Tube for every patient.

IMPORTANT NOTES:

1. Users should review complete manufacturer's guidelines for equipment disinfection/sterilization found in the user's manual.
2. Users should review EndoSheath® Technology installation/removal process found in the user's manual.

WARNING: This chart is only for reprocessing of Vision Sciences® endoscopes using EndoSheath® Technology

Remove endoscope from Sheath and place in a clean/Sterile area. Do not handle the endoscope with contaminated gloves

After removing the Sheath, Inspect the endoscope insertion tube and distal bending section and confirm these areas are dry and undamaged.

NOTE

If the endoscope was dry when the sheath was fitted it will be dry when removed. If moisture is observed, this could indicate a breach of the sheath and high level disinfection can be considered. If high level disinfection is decided upon, the endoscope must be prepared according to instructions in the user manual.

CLEANING AN INTERMEDIATE LEVEL DISINFECTION (after each procedure)

Gently wash all external surfaces of the endoscope with an appropriate instrument grade detergent or EndoWipe™ Enzymatic sponge

After washing thoroughly rinse the outside of the Endoscope with clean lukewarm water.

Wipe down the entire Endoscope with Gauze soaked in 70% ethyl/isopropyl alcohol or an EndoWipe™ Towelette . Ensure full coverage of alcohol

Ensure all external surfaces of the Endoscope are dry prior to installing another Sheath.

LEAK TESTING (If a leak is suspected & if high level disinfection is needed)

Connect the leak tester to the endoscope's EtO/vent valve. Push down and rotate the leak tester connector clockwise until it is secured.

Pressurise the Endoscope. Ensure leak tester's valve is closed. Pump the hand bulb until the needle reaches the green section. Maintain pressure for 10 seconds, observing the needle position. Endoscope may require several pumps of the bulb to completely pressurise

If the needle position remains steady. Immerse the entire scope in water and observe if for 30 seconds. Angulate the distal bending section up and down while the Endoscope is immersed. The absence of air bubbles confirms the scope is air tight. Remove from water and open the leak tester's valve. Ensure the needle on the pressure gauge fails to zero and disconnect the leak tester from the endoscope.

NOTE

If the pressure decreases the leak tester connection may be loose or the pressure valve on the leak tester may be open Re-attach the leak tester. If the symptoms persists, contact Genesis Medical. A small stream of bubbles indicates a leak in the endoscope that was not detected by pressure gauge. Do not continue to use a leaking endoscope and contact Genesis Medical for repair.

EndoSheath® Technology

In the event that high level disinfection/sterilization is required, please refer to the protocols in the user's manual for proper steps to ensure complete and efficacious reprocessing.

Vision-Sciences, Inc.
40 Ramland Road South / Orangeburg, NY 10962
Telephone: 800-874-9975 / 845-365-0600 / Fax: 845-365-0620
E-Mail: info@visionsciences.com

Genesis Medical Ltd
7 Trojan Business Park
Cobbold Road
London NW10 9ST
Tel: +44 (0)20 8451 4100
Fax: +44 (0)20 8451 4115
Website: www.genmedhealth.com

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Feature

Feature

A 21st century nosocomial issue with endoscopes

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Anne Marie Noronha, senior associate[1],
Steve Brozak, president[1]

Author Affiliations

1WBB Securities, 67 Walnut Avenue, Clark, NJ 07066, USA

sbrozak@wbbsec.com

Endoscopic procedures provide lifesaving diagnostic information, but do they put patients at unnecessary risk of deadly infection from cross contamination?

On 3 January 2014 the results of a year long investigation by the US Centers for Disease Control (CDC) into an outbreak of New Delhi metallo-β-lactamase (NDM)-producing carbapenem resistant Enterobacteriaceae (CRE) were released. Of 69 patients with confirmed CRE infections, 29 went to Advocate Lutheran General Hospital (ALGH) for the same procedure—an endoscopy.[1] The endoscopy itself is not dangerous, but the current cleaning process used between procedures leaves patients susceptible to infection and troubles many healthcare practitioners.

With more than 18.6 million gastrointestinal endoscopies and at least a half million bronchoscopies every year in the US alone,[2] medical practitioners must take the utmost care during the cleaning process between patients, especially with the emergence of superbugs such as CRE. But the safety profiles of the cleaning protocols are less than acceptable in preventing life threatening outbreaks. The endoscopes are frequently the means for facilitating pathogenic cross contamination between patients—making the case at ALGH far from unique.

The threat of cross contamination may not be visible to a clinician from personal experience alone, but broader and more comprehensive studies show that the cleanliness of endoscopes varies greatly. A mid 2013 study reported that about 15% of endoscopes in US hospitals failed to achieve an accepted standard of cleanliness after liquid reprocessing (the prevailing disinfection process used between patient procedures).[3] In this study, duodenoscopes were the dirtiest at a 30% contamination rate, and colonoscopes were the cleanest at a 3% contamination rate.[3]

All in all, reprocessing is time consuming, labor intensive, expensive and, most importantly, susceptible to failure. Among the most problematic features of an endoscope are the luminal channels, which often become contaminated by endoscope accessories.[4] The lumen are difficult to access and can easily harbor pathogens through multiple reprocessing procedures,

even when the protocol is followed correctly.4 Not only must the cleaning protocol be followed strictly, but the equipment and reprocessing environment also must be well maintained.5 Disinfectants and cleaning materials for endoscopes are often contaminated themselves in these incidents.6

Ironically, the commonly used liquid reprocessing procedure is sometimes called "liquid sterilization" even though it does not sterilize the instrument. According to guidelines from the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) the protocol requires up to 43 steps and, according to another study, over half an hour of labor. 5 7 To begin, debris is removed during pre-cleaning. Next, leak testing makes sure that all internal channels are intact and that no holes contribute to instrument contamination. The scope then must be taken apart to allow access for manual cleaning, which removes any foreign material that may interfere with disinfection. The endoscope is then immersed in a high level disinfectant.5 The disinfectant must be potent enough to remove contaminants, yet gentle enough to preserve the integrity of the instrument, since a disinfectant that is too concentrated may decrease the life span of the instrument.8 The scope is then rinsed, dried, and stored.5 The SGNA also offers several guidelines for maintaining the cleaning reprocessing environment to help make reprocessing as effective as possible.5

Regrettably, endoscope contamination is not a new phenomenon. In 2006 Seoane-Vazquez and colleagues reported meta-data analysis on all available contamination incidents in the US during the 30 year period between 1974 and 2004.6 Research showed that 10 989 patients were exposed to a contaminated instrument and 740 patients were contaminated (although not all reports stated how many were exposed).6 The implicated types of endoscopy varied. Bronchoscopy and gastrointestinal endoscopy contributed the highest numbers of incidents (see table 1⇓); and upper GI endoscopy infected the most patients per patients exposed (see table 2⇓).6 The infectious agents identified the most were *Mycobacterium tuberculosis* and *Pseudomonas aeruginosa*, both of which are life threatening and have associated antibiotic resistant strains.6

Table 1 Patients exposed to endoscope related contamination by type of intervention (1974-2004

Intervention	Outbreaks reporting patients contaminated
Arthroscopy	1
Bronchoscopy	35
Cystoscopy	3
Endoscopic retrograde cholangiopancreatography	7
Lower gastrointestinal endoscopy	12
Upper gastrointestinal endoscopy	10
Gastrointestinal endoscopy*	1
Total	69

*Outbreaks not included in lower or upper GI endoscopy.

Data only include outbreaks that also report patients exposed.

Adapted from: Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. *Curr Med Res Opin* 2006;22:2007-21.

Table 2 Ratio of patients exposed to patients contaminated by type of intervention

Intervention	Number of outbreaks	Number of patients exposed	Number of patients contaminated	% contaminated
Arthroscopy	1	352	7	2.0
Bronchoscopy	15	4001	270	6.7
Cystoscopy	2	773	25	3.2

Endoscopic retrograde cholangiopancreatography	4	554	38	6.9
Lower gastrointestinal endoscopy	4	4179	42	1.0
Upper gastrointestinal endoscopy	3	1130	107	9.5
Total	29	10<thin>989	489	4.4

Note: Data only include outbreaks that report patients exposed and patients contaminated.

Adapted from: Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. *Curr Med Res Opin* 2006;22:2007-21.

Owing to limited surveillance, limited reporting, and lack of immediate clinical symptoms of patients, experts agree that the endoscopic cross contamination is significantly under-reported and its incidence cannot be accurately determined.6 Outbreaks that are recognized usually involve severe or unusual pathogens, which then prompt thorough investigations.6 If an older patient contracts tuberculosis, a doctor is not likely to suspect that the patient's latest endoscopy is implicated, even though *M tuberculosis* transmission represents a significant proportion of recent outbreaks.6 Even so, since 2000, several outbreaks of life threatening pathogens have been traced to contaminated endoscopes in facilities throughout the US and Europe.9 10 11 12 13 14 15 16 17

In 2009, 11 000 patients were notified of possible infection after the US Department of Veterans Affairs (VA) learned through an internal investigation that only 42.5% of its endoscope reprocessing units were adequately cleaning endoscopes.18 Because US government agencies are generally required to publicly divulge their findings, the VA's information may provide better representation of all endoscope facilities, including those that are not subject to the same mandated reporting.

Infections resulting from scope contamination break the trust between patients and doctors and place a financial burden on healthcare institutions. Two VA patients (one with hepatitis C and the other with HIV) successfully sued the federal government.19 20 The statute of limitations meant an unfortunate veteran who was infected with hepatitis B could not seek compensation because the time limit had expired before he learned that he had been infected.20

Following an outbreak last year at the Neosho Memorial Regional Medical Center, substandard scope cleaning was detected and 244 patients were notified of possible exposure to HIV, hepatitis B, and hepatitis C.17 In 2002, an outbreak of *P aeruginosa* infected at least 32 of 414 exposed patients at Johns Hopkins Hospital and may have played a role in three deaths.10 At an unnamed Texas hospital in 2009, an arthroscope transmitted the same bacteria to seven patients.11

Among those healthcare organizations that were able to determine the exact cause of their disease outbreaks, the lumen of the endoscope was most often found to be the chief culprit.4 The lumen, through which auxiliary equipment such as biopsy forceps can be threaded, is difficult to clean and inspect, making it an easy place for bacteria to hide.4 In 2001, three consecutive outbreaks in one French hospital were caused by a loose port at the entrance of one luminal channel.12 The resulting infection rates were 117 out of 418 scoped patients.12 In 2003, two implicated bronchoscopes in a different French hospital had damaged lumens, which were promptly replaced. In this incident, 4 of 16 scoped patients were infected.13

Despite the high rate of endoscope contamination and published outbreaks resulting from such contamination, the medical community tends to attribute mishaps to negligent cleaning and human error. The Emergency Care Research Institute, which lists inadequate reprocessing of endoscopes as one of its "2014 Top 10 Technology Health Hazards," asserted that guidelines should be continuously reviewed and technicians should be better trained.21 However, this advice is over two decades old and the problem still persists. The CDC has also been warning about cross contamination since 199122 and other medical organizations have concurrently tightened procedural guidelines.23 24 Meanwhile, the proportion of incidents caused by equipment defects and cleaning equipment contamination (not human error) has since risen, according to the 30 year US based study.6 Additionally, not all incidents covered in the study were reported to have had an in-depth investigation into the causality of events; thus, human error could be an assumption in many of the cases.6

As past experience demonstrates, even the most stringent liquid reprocessing guidelines do not prevent outbreaks. The complexity of reprocessing protocols and the intricacy of endoscope design are inherent flaws, because they foster statistically predictable failures that allow pathogens to persist on the endoscope, particularly in the luminal channels[4 12 13] and in the cleaning equipment and detergent.[6]

One of the very few positive outcomes of a contamination incident is the change of disinfection practices that follows. After its superbug outbreak, the ALGH switched to ethylene oxide gas sterilization.[1] Alternatively, several other facilities in the US and the UK have begun using sterile disposable sheaths on scopes and have reported improvements in safety.[7 25 26 27]

The sheath provides a single use sterile barrier between the scope and the patient without hindering functions such as visualization and biopsies. The device incorporates a sterile "working channel" that allows equipment such as biopsy forceps to pass through unhindered.[27] Studies show that using the sheath, along with a simple alcohol wipe down between uses, guarantees sterility, offering a vast improvement over current decontamination procedures.[26 28] Even if there is a defect in the integrity of a single sheath, research confirms that the second sheath prevents contaminants from infecting the next patient.[25] The central idea behind the sheath is that a pathogen cannot overcome it. Because each sheath is used only once, pathogens cannot hide on the outside of sheaths or become resistant to disinfecting liquids. One added benefit to using sheaths, which no other decontamination protocol offers, is protection against prions, such as that which causes Creutzfeldt-Jakob disease.[28]

By using sheathed endoscopes, healthcare facilities will spend less on labor and equipment[7 27] and avoid exposure to noxious chemicals.[7 26] Although acquiring new endoscopes that accommodate sheaths may require an initial investment, the scopes are less expensive than unsheathed models and better in terms of long term benefits in patient care, efficiency, and lower operating costs.[27] The sheath eliminates unreliable and cumbersome reprocessing, condensing the protocol into just a few steps, and reduces reprocessing time by up to 31 minutes.[7] It also is more cost effective, reduces repair costs, and decreases investment in multiple scopes that are out of operation while being cleaned.[7 26 27]

Other sterilization methods exist for endoscopes, but each has its drawbacks in terms of safety, efficiency, and cost. Ethylene oxide gas sterilization is a toxic and carcinogenic process, requiring additional time for a post-sterilization aeration period.[8] Hydrogen peroxide gas plasma sterilization also has a long processing time, is expensive, and can be corrosive to certain materials. Neither of these methods protects against prions.[8]

The advent of antibiotic resistant bacteria such as CRE and deadly viruses requires that cleaning standards be continuously improved. Just about every invasive instrument we use is sterilized better than the endoscope. Syringes and needles are almost universally disposable and many surgical instruments are subjected to intense heat and pressure between uses. Endoscopy demands the same standards, because the instruments come into contact with or break the delicate mucosal membranes.

In 2013, the UK Department of Health (DH) recommended a "tracking, traceability and audit trail" designed to systematically expose instances of cross contamination before becoming widespread.[21] US outbreaks between 2000 and 2004 lasted an average of 84 days,[6] and the recent CRE outbreak at ALGH lasted the full year,[1] highlighting the importance of a vigilant surveillance system. The system proposed by the DH will provide the medical community with a more accurate and active survey of epidemiology, and hopefully push its constituents to replace liquid decontamination with a more effective alternative.

The *BMJ* is an appropriate venue for this discussion because of its undeterred criticism of conformist practices with the intent of improving healthcare. In 2012, the *BMJ* addressed nosocomial infection in an article titled "Dirty, deluded and dangerous" by Gary L French,[29] which exposed the recent trend of doctors who wash their hands much less frequently than expected.[30]

The issue of scope cross contamination and the growing incidence of negligence in hand washing have a common historical background. In the 1800s, most European physicians rejected the theories of Ignaz Semmelweis,[31] who proposed that hand washing would lower the postpartum mortality rate.[32] Since the advent of antibiotics, doctors have paid less attention to the value of meticulous sterilization.[29] However, with the recent appearance of superbugs, we need to be more mindful of careful

sterilization.

We must not make the same mistake as Semmelweis's contemporaries, who remained passive as their patients suffered the consequences of doctors with dirty hands while a simple, lifesaving alternative was sensible, affordable, and available. Like hand washing in Semelweis's day, better procedures for cleansing and even sterilizing scopes between uses are mandatory to prevent cross contamination, prevent infection, and potentially save lives.

Notes

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Footnotes

- Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.
- Provenance and peer review: Not commissioned; externally peer reviewed.

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Urinary tract infection following flexible cystoscopy: a comparison between sterilised cystoscopes and disposable sterile sheaths

Steve P McCombie; Jack P Carmichael; Srijit Banerjee; Sarah J Wood

Department of Urology, Norfolk and Norwich University Hospital, UK
Email:steve.mccombie@doctors.org.uk

Abstract

Objective: The objective of this article is to compare the incidence of post-cystoscopy urinary tract infections (UTIs) between cystoscopes sterilised between patients and cystoscopes that use removable sterile sheath technology.

Patients and methods: A total of 200 patients undergoing flexible cystoscopy at the Norfolk and Norwich Hospital (Norwich, UK) between November 2011 and March 2012 were identified prospectively as part of an ongoing audit of the department's services. One hundred patients were recruited from day procedure lists, using KeyMed® cystoscopes sterilised between patients (sterilised scope, SS); 100 patients were recruited from a 'one-stop' urology clinic, using a Vision Sciences® CST-5000 cystoscope with disposable sterile Endosheath® technology (removable sheath, RS). Mid-stream urine (MSUs) samples and patient symptoms were recorded prior to the cystoscopy and at least three days following the cystoscopy.

Results: No significant difference was found in the incidence of new MSU-confirmed UTI (2.7% (SS) vs. 2.0% (RS)). In those undergoing their first cystoscopy, no significant differences were found in either new symptoms (34.1% (SS) vs. 36.7% (RS)) or requirement for antibiotics (13.6% (SS) vs. 13.0% (RS)).

Conclusion: Flexible cystoscopy using removable sterile sheath technology does not have a higher incidence of UTI compared to a cystoscope sterilised between patients. The introduction of cystoscopes using this technology can therefore safely transform flexible cystoscopy into an outpatient clinic procedure.

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Conflict of interest
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Out-patient flexible cystoscopy using a disposable slide-on™ endosheath system

MICHAEL KIMULI, STUART N LLOYD

Pyrah Department of Urology, St James's University Hospital, Leeds, UK

ABSTRACT

INTRODUCTION The aim of this study was to investigate the feasibility of out-patient flexible cystoscopy.

PATIENTS AND METHODS Twenty-seven patients awaiting diagnostic or check cystoscopy in Leeds, UK were invited to undergo out-patient flexible cystoscopy using a CST-2000 Flexible Cystoscope (Vision Sciences; Natick, MA, USA) using the sterile single-use slide-on™ disposable endosheath endoscope system (EndoSheath®; Vision Sciences). The performance of the cystoscope was evaluated, and the patients' experiences were documented using a questionnaire.

RESULTS The out-patient setting proved to be ideal for flexible cystoscopy. The cystoscope was rated highly for image quality, ease of use and handling. All patients complimented us on the service and preferred out-patients to a day-ward or theatre attendance.

CONCLUSIONS This study demonstrates that it is possible to perform out-patient flexible cystoscopy safely, economically and efficiently with the aid of a disposable endoscope system.

KEYWORDS

Flexible cystoscopy – Vision Sciences – Disposable endoscopy sheaths – Slide-on™ endosheath system

CORRESPONDENCE TO

Stuart N Lloyd, Consultant Urologist, Pyrah Department of Urology, St James's University Hospital, Leeds LS7 9TF, UK
E: slloyd140@btinternet.com

Flexible cystoscopy is the most frequently performed urological procedure both as a diagnostic and surveillance tool. Freely available facilities to flexible cystoscopy is fundamental to modern urological practice but this is often limited by access to facilities, sterilisation and instrumentation resulting in significant waiting times for the procedure delaying diagnosis and treatment. Most units perform flexible cystoscopy in a day-ward theatre setting, others in purpose-built endoscopy units, few in the out-patient setting. Within our unit, flexible cystoscopy is performed in day-ward theatres, waiting times for non-urgent flexible cystoscopy has reached 9 months. Purchasing and servicing a large number of instruments was considered costly. Moving flexible cystoscopy into an out-patient setting with the implementation of the new Vision Sciences flexible cystoscope using slide-on™ endosheath system may overcome these difficulties and provide an opportunity to improve efficiency.

This paper reports our initial experience with this new device comparing it with standard flexible cystoscopy in an out-patient setting.

Patients and Methods

Twenty-seven patients on the day-case waiting list for diagnostic flexible cystoscopy were randomly chosen to be part of the pilot for the out-patient flexible cystoscopy list. Initially, small numbers were listed to establish the processes; the last list accommodated 10 patients comfortably. All patients were given an information sheet in the waiting area prior to the procedure. They were interviewed using a simplified assessment sheet and consented by the operator (Appendix 1). Patients did not fully change as in the day-ward setting but removed their lower half garments in the treatment room behind a screen.

The Vision Science CST-2000 flexible cystoscopy was used for all procedures. At first glance, the flexible cystoscope looks similar to existing instruments but closer inspection reveals several key differences (Fig. 1A–D). The cross-section of the instrument is crescenteric and measures 13.8-F by 16.8-F. It has a lever to lock onto the disposable sheath and a depression valve for irrigation. The sheath incorporates a 6-F working channel for biopsy and ureteric stent removal.

Key Points:-

- To demonstrate that Outpatient flexible cystoscopy was a feasible practice
- 27 patients awaiting diagnostic or check cystoscopy in the Leeds area were invited to attend an Outpatient Clinic to evaluate the Vision Sciences CST2000 scope that uses the Endosheath system
- The performance of the system was evaluated and patient feedback obtained through questionnaire
- The results were positive indicating Outpatients scenario was ideal for flexible cystoscopy of this nature
- The system was rated highly for image quality, ease of use and handling
- Patients complimented the service and preferred Outpatient setting to day-ward or theatre based procedure

Conclusions:-

- The Vision Sciences system makes it possible to perform outpatient flexible cystoscopy, economically and efficiently with the aid of a disposable Endosheath system

Microbiologic Assessment of Disposable Sterile Endoscopic Sheaths: Prospective Clinical Trial

Alvarado CJ, Anderson AG, Maki DG. Microbiologic assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing: a prospective clinical trial with nasopharyngoscopes. *Am J Infect Control* 2009;37:408-13.

In this article, Alvarado et al described a clinical trial that included a microbiologic assessment of the ability of the Slide-On® EndoSheath® Technology (Medtronic ENT, Jacksonville, FL) to provide protection against bacterial contamination of flexible nasopharyngoscopes. Three 30-mm Olympus nasopharyngoscopes (ENF Type P4, Olympus America, Melville, NY) were used while covered with an EndoSheath® barrier to examine the nasopharynx and larynx of 100 different, randomly selected patients. The surface of the head and shaft of each nasopharyngoscope was wiped to obtain two samples for culture at each of the following times: before application of the EndoSheath® Technology and the endoscopic examination, immediately after the examination and removal of the EndoSheath® disposable, and after a disinfection procedure consisting of the following steps: vigorous wiping of the endoscope with an enzymatic detergent, rinsing with running tap water, drying with gauze, wiping with gauze soaked in 70% ethanol, and air drying in a vertical position. All samples were plated on 5% sheep blood agar and incubated for 72 hours at 37°. Bacterial colony types were enumerated and identified by using standard methods. The study also included leak testing of the 100 used disposable sheaths removed from the nasopharyngoscopes and of 20 unused sheaths taken from the clinic inventory. The barrier integrity of the EndoSheath® Technology was assessed by using a pressure decay system (138 ± 2 inches of water [5 lb per square inch]).

Bacteria grew in cultures of 16 head and 6 shaft samples obtained before the endoscopic procedure, 13 head samples and 1 shaft sample taken immediately afterward, and no samples obtained after the disinfection procedure. The contamination found was low level (2 to 100 colony-forming units) and due primarily to skin commensals, mainly coagulase-negative *Staphylococcus* and *Bacillus* species. One sample was positive for *Staphylococcus aureus*; none showed gram-negative bacilli or fungi. None of the 120 used or new sheaths lost barrier integrity on leak testing. Alvarado et al noted that not a single leak or tear had been detected in the total of 755 sheaths in their study and all previously reported clinical trials in which the EndoSheath® Technology was used.

In light of their findings, the researchers concluded that use of the EndoSheath® Technology followed by proper cleaning and intermediate disinfection with 70% ethanol can provide a safe, patient-ready nasopharyngoscope, with reliable protection against contamination by virulent bacteria pathogens such as methicillin-resistant *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and mycobacteria species and by viruses likely to be present in the respiratory tract. Alvarado et al also suggested that the acquisition costs of disposable sheaths would be offset by avoidance of high-level reprocessing of flexible endoscopes, which is expensive and may expose health care workers to toxic disinfectants; by reductions in endoscope downtime; and, possibly, by a decrease in costs associated with inadequate high-level reprocessing practices.

Endoscope Sheaths as Viral Barriers: Laboratory FDA Study

Baker KH, Chaput MP, Clavet CR, Varney GW, To TM, Lytle CD. Evaluation of endoscope sheaths as viral barriers. *Laryngoscope* 1999;109:636-9.

The aim of this bench study conducted by scientists at the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA) was to characterize virus transmission through otolaryngologic endoscope sheaths in which a hole or tear had been made with an excimer laser or acupuncture needle. EndoSheath® Technology (n = 22) with a hole or tear ranging from 2 to 84 µm were applied to an endoscope, which was then submerged in a high-titer virus suspension (108 viruses/mL). The inside of each EndoSheath® barrier and the endoscope on which it had been placed were then rinsed separately to determine the amount of any virus that had penetrated through the hole.

A sequential test was also conducted. In this experiment, a virus challenge was first performed outside an EndoSheath® disposable in which a 30-µm hole was created before it was applied to an endoscope. The EndoSheath® Technology was then removed from the possibly contaminated endoscope, and a second EndoSheath® barrier, in which a 20-µm hole had been made in the same location as the 30-µm hole in the first EndoSheath® disposable, was placed on the endoscope. Another virus challenge was conducted to determine whether any virus would pass outward through the second sheath.

The first experiment found that small volumes of virus-containing fluid penetrated through the holes or tears in the EndoSheath® Technology and that up to 45% of passed virus particles could be recovered from the endoscope after removal of the EndoSheath® Technology. In the sequential test, virus was found on the second disposable barrier in only one case. Most important, according to the researchers, no virus was found outside the second sheath.

The FDA researchers recommended that an endoscope reprocessing step be combined with use of disposable sheaths. They also said, however, that their data indicated that the step need not be high-level disinfection. Instead, they concluded that meticulous cleaning of an endoscope followed by intermediate-level disinfection should provide a safe instrument for otolaryngologic endoscopy.

Genesis Medical Ltd
7 Trojan Business Park
Cobbold Road
London NW10 9ST

t 020 8451 4100
f 020 8451 4115
e mail@genmedhealth.com
www.genmedhealth.com

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Infection Control of Sheathed Scopes as raised in the CfPP 01-06 guidelines - Issues relating to Vision Sciences (VSI) Flexible Endoscopes

Decontamination of flexible endoscopes: Operational management manual

- *This document is not produced in any way in conjunction with the DoH.*

What is the CfPP document?

- The CfPP published guideline *'offers best practice guidance on the management and decontamination of flexible endoscopes… '*(14304 – Page 6). *'It supersedes the relevant parts of (HTM) 2030 document*...' Page 7.

- The structure of the document is to divide in to five key areas. Vision Sciences are not a producer of EWD [endoscope washer disinfectors] so these are not discussed except in relation to their use with VSI endoscopes.

14091/14188 (Page 49/50) *looks specifically at non-channelled Nasendoscopes.*

- It states that because of the nature of their use, these non-channelled scopes are manually cleaned with an appropriate medical grade, endoscopic disinfectant.
- Vision Sciences endoscopes are non-channelled so these guidelines apply.
- In addition, as these scopes are non-channelled they also do not require the use of drying cabinets due to the possibility of bacterial contamination on their surface not being replicated in the absence of liquid water.
- It also states that 'as long as direct or indirect recontamination with patient body fluids does not occur, no maximum time of storage before reprocessing can be specified.'

These key statements in relation to ALL VSI endoscopes using Endosheath® Technology

- VSI scopes are also channel-less and as such can be considered in the same way whether it is in Bronchoscopy, Cystoscopy, Trans Nasal Oesophagoscopy and of course Nasendoscopy
- On discussion with some leading UK based experts in decontamination that these principals can apply to all VSI endoscopes regardless of therapeutic area.
- On review of the validated processes and protocols outlined by VSI, the experts agreed the Endosheath® Technology maintained the highest levels of patient and user safety
- Contact details of the experts are available on request for validation of these opinions

What is the VSI Endosheath® product offering?

- VSI Endoscopes are channel-less flexible endoscopes over which a specific external Endosheath® is fitted
- This provides a sterile insertion tube in contact with the patient rather than (usually) a high level disinfected scope provided by the EWD.
- The Endosheath®/endoscope combination means the scope never directly makes contact with the patient.
- The sterile working channel is incorporated in the Endosheath® and never touches the endoscope
- Each Endosheath® provides a single use sterile product
- The working channel is new and sterile for each patient
- The risk of cross contamination is vastly reduced because the working channel is disposed of after each case

CfPP guidelines – specific points of relevance

Personnel

Section 14069 **(Page 9)** *states Training should be provided for all staff involved in the decontamination of flexible endoscopes.*

- Genesis Medical provides comprehensive training packages in the form of presentations, supporting materials and training competencies for the users of its products, to ensure they are fully equipped to use the product correctly and in accordance with the validated protocol.

Types of EWD and cycles

Section 14073/14165 **(Page 17)** *discusses the use of EWD devices.*

- VSI Endoscopes can be re-processed in an EWD
- Like all manufacturers of endoscopes, VSI would firstly ensure chemical compatibility and functional compatibility with the specific EWD

Size and Numbers of EWD's

Section 14076/14168 **(Page 23)** *discusses the need to assess how many EWD's a facility may require.*

- There is no formal requirement for VSI scopes to undergo EWD reprocessing between every case (providing the endoscope is not grossly contaminated)
- The overall number of EWD machines required may be reduced as the main reason for multiple EWD's is to maintain efficiency within the Endoscopy service on offer (and indeed Endoscopes as highlighted in section 14169 and 14170.) **(Page 24)**
- VSI scopes are reprocessed in between cases using a validated protocol consisting of intermediate level disinfection cleaning regime combined with

- an aseptic technique for loading a sterile Endosheath® for each patient highlighted in sections 14169 and 14170 **(Page 24)**.

Reprocessing

*14078/14173***(Page 27)** *points to the use of disposable or re-usable reprocessing accessories, such as cleaning brushes, cleaning tools, endoscope valves and water bottles.*

- The guidelines refer to the need to for single use items, which can incur additional cost.
- Reusable items for these purposes also incur on-going costs as functional inventory must be maintained, meaning additional cleaning and maintenance costs.
- VSI scopes have no channels and removes the need for many of these items

EWD operation, and endoscope storage and transportation

14083 **(Page 33)** *points out the difficulties in inspection of flexible endoscope long narrow lumens* (working channels) *and that these require connection to the EWD.*

- VSI endoscopes circumvent these difficulties by removing the working channel from the endoscope and placing them as a single use sterile working channel within the Endosheath®

Decontamination of Endoscopes

14186 **(Page 41/42)** *discusses the need of the user to follow the manufacturers' guidelines for cleaning.*

- VSI provides this in data form, presentation/visual aids and formal training competency documents
- Conventional channelled endoscopes require essential manual cleaning due to the direct contact with the patient
- VSI endoscope cleaning is prophylactic when used with the Endosheath® in accordance with the manufacturer's guidelines.

*14187****(Page 42)*** *discusses in depth the process stages of an EWD*

- This is 9 specific points which must be performed exactly in order to prevent failing the cycle or alarming the EWD due to incorrect set up - VSI endoscopes removes this issue.

14190 **(Page 45/46)** highlights issues in the transportation of HLD cleaned flexible endoscopes

- Additional equipment (transportation trays with a two covers) is required for moving contaminated/decontaminated endoscopes.
- These trays will also require cleaning and decontamination.
- Using VSI endoscopes that do not require the routine use of EWD's removes the issues highlighted here with transportation

Decontamination of Nasendoscopes

14091/14188 **(Page 49/50)** *looks specifically at non-channelled Nasendoscopes.*

- It states that because of the nature of their use, these non-channelled scopes are manually cleaned with an appropriate medical grade, endoscopic disinfectant.
- Cleaning should also be undertaken irrespective of the use of covering sheaths, but crucially **does not exclude the use of such sheaths**.
- In addition, as these scopes are non-channelled they also do not require the use of drying cabinets due to the possibility of bacterial contamination on their surface not being replicated in the absence of liquid water.
- It also states that 'as long as direct or indirect recontamination with patient body fluids does not occur, no maximum time of storage before reprocessing can be specified.'

These are significant and key statements in relation to ALL VSI endoscopes using Endosheath® Technology

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- On review of the validated processes and protocols outlined by VSI, the experts agreed the Endosheath® Technology maintained the highest levels of patient and user safety
- Contact details of the experts are available on request for validation of these opinions

Sections 14095 **(Page 56)** *to 14099/14206* **(Page 65)** *look at chemical compatibility with EWD's as well as enzymatic detergents, and flexible endoscopes*

- A full list of compatibility is available upon request
- VSI endoscopes are generally compatible with the common used chemicals in the UK.

Traceability

- All VSI Endosheath® packaging have tracking LOT number labels in triplicate on the exterior of the sterile package
- Endosheath® Tracking can then be maintained to the highest standards, in addition to any tracking/traceability brought about by periodic use of the EWD system

An example of the Journey of an endoscope through the system

Section 14218 **(Page 76)** *outlines the manual cleaning phase of scope reprocessing,*

- VSI endoscopes do not require routine use of EWD systems
- Section 14218 outlines the manual cleaning phase of scope reprocessing, which can be maintained with the Vision Sciences' scopes.
- The process would routinely change to the appropriate protocol for the specific endoscope and Endosheath® combination being used, as outlined in the training competencies and resources provided by VSI
- IF gross contamination is suspected or the local protocol dictates periodic use of the EWD system then this can be conducted in accordance with CfPP 01-06's guidelines.

Summary

- The unique nature of the VSI Endosheath® Technology aseptically fitting sterile sheaths incorporating the working channels on the Vision Sciences non-channelled scopes are different from traditional channelled flexible endoscopes.
- Sheaths fitted over non-channelled scopes are acceptable in the document. This means that Clinicians can be assured of maintaining adherence to the guideline, whilst significantly reducing risk of cross bio-contamination and improving operating efficiency.